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ACCESS TO MEDICATION: THE PERSPECTIVES OF PEOPLE WHO RESORT TO JUDICIAL PROCEEDINGS[1]

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ABSTRACT
The present study is an interpretative case study developed to describe the experiences of people who have resorted to judicial proceedings to gain access to medications in the Unified Health System. Data were collected through semi-structured interviews in the homes of eight individuals who have used this approach, who lived in a city in the southwest of the State of Goiás. The experience of access to medications was marked by barriers that are interconnected to the different levels of the health system; they involve organizational and assistance aspects related to information, embracement and resolution. The need for continued treatment of chronic conditions and financial difficulties were the determining factors for participants to resort to judicial proceedings. The need to improve embracement and communication among the health teams involved in access to medications, and to qualify health professionals for a broader understanding of pharmaceutical care in the Unified Health System, was observed.

Keywords: Right to health. Pharmaceutical services. Health services accessibility. Unified Health System.

INTRODUCTION

The United Nations considers access to essential medications to be an indicator that represents the quality and resolution of health systems and the realization of the right to health[(1)]. Therefore, ensuring equitable access to these drugs is a challenge and an essential component of the systems[(2)]. In Brazil, access to essential medications is guaranteed by the Unified Health System (SUS) through the Federal Constitution.

In view of difficulties in obtaining the drugs prescribed for the effective treatment of diseases, the phenomenon of the judicialization of access to health has been discussed in Brazil, and among the main areas that generate legal proceedings is pharmaceutical assistance[(3)].

The pharmaceutical assistance guaranteed by SUS consists of three financing components: basic, strategic and specialized[(4)]. The medications that make up the three elements are described in the National List of Essential Medicines (RENAME), which is organized in the form of official public lists. RENAME presents all the essential medications and supplies made available by SUS. Also, it is responsible for guiding the definition of public policies for access to medications, according to the specific needs of the population[(4)].

Users can gain access to the medications in the public official lists in the health units through the SUS process for access to medicines. However, despite advances in Brazilian public pharmaceutical policies, effective access is far short of what is desired, because some users still face social and economic barriers that impede the safety and resolution of therapeutic plans[(5)].

Users have become more actively involved in the search to ensure access, and have resorted to the judicial and executive branches to obtain medications, whether or not they are on the public official lists. This gives rise to two possibilities: judicial and administrative routes[(6)].

[1]Extracted from the dissertation entitled: The perspective of users on the access to medicines through court proceedings, submitted to the Graduate Program Master of Science and Environmental Health of the Pontifical Catholic University of Goias, in 2013.

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If on the one hand, the judicial route represents an advance in the exercise of citizenship by users, on the other, there is inconsistency among judicial decisions, public health policies and SUS guidelines[7].

Thus, access to medications by judicial means has been debated by managers, magistrates and health professionals, and represents a challenge for SUS, not only regarding of the costs of lawsuits but also because it reveals weaknesses in the legal and normative spheres of the public health system[7].

The present study was developed to describe the experience of searching for access to medications in the Unified Health System from the perspective of people who have resorted to judicial proceedings. The results contribute to highlighting the social reality experienced by individuals who have used this route and present the path taken in the search for the drugs. Also, they allow the identification of factors that motivate users to use the judicial route.

It is necessary to understand the motivations that lead users to use this way, and also to point out the measures to be adopted by health managers and professionals to improve access to medications and result in a reduction in legal demands. Such requests reveal interference in management that should be overcome by all the institutions involved, especially by SUS agencies and, in particular, management of pharmaceutical care.

Therefore, the objective of the study was defined as the description of experiences of people who resorted to judicial proceedings to access medications in the Unified Health System.

METHODOLOGY

This is an interpretative case study conducted according to the methodological assumptions of modern hermeneutics, which considers knowledge as a historical construction of dialogical and intersubjective social relations between the researcher and the participant[8]. The central concern of this type of scientific research is to describe and explore one or more cases in their actual context to understand their complexity[9].

The study focused on eight cases of families that resorted to judicial proceedings to gain access to medications in a municipality located in the southwest of the State of Goiás, Brazil, from January to December 2012. The following inclusion criteria were considered: people aged 18 years or over, for whom at least one drug was requested, and/or a family member responsible for filing the judicial process at the 2nd District Prosecution Office of the municipality under study.

To select the participants, the legal proceedings filed at the Municipal Health Department that were judged and approved in the 2nd District Prosecution Office in the city under study were reviewed. Those who had requested at least one medication were included, resulting in a total of ten processes.

All those responsible for the lawsuits were effectively contacted via telephone: eight agreed to participate in the survey; two refused to participate because they feared interruption of the supply of medications by the municipality.

The eight processes were for people with chronic diseases, mainly related to the circulatory and neurological systems. A total of fourteen drugs were demanded. Eleven were not present in RENAME in the study period (ursodeoxycholic acid 300 mg, clopidogrel 75 mg, levodopa/benserazide hydrochloride 100/25 mg, trazodone hydrochloride 50 mg, memantine hydrochloride 10 mg, valsartan/amlodipine 320/10 mg, triflusal 300 mg, atenolol/chlorthalidone 50/12.5 mg, propatilnitrate 10 mg, sodium pantoprazole 40 mg, and domperidone 10 mg). Only three drugs were part of RENAME (simvastatin 20 mg, enalapril 20 mg, and oxcarbazepine 600 mg).

Experiences regarding access to medications in the eight cases analyzed was described from the perspective of five relatives and four patients; all of the patients were financially dependent on their families for the purchase of medications. Of the patients, five had complete dependence on family care related to daily living activities, and four were not in the physical and/or cognitive condition for effective participation.

Individual semi-structured interviews were conducted in depth from January to August 2012. The interviews were conducted by the principal investigator, who had previously undertaken training, under the supervision of one

of the researchers, who is specialized in collecting qualitative data.

The interviews were carried out in the participants' homes based on a script that included socioeconomic variables (age, educational level, individual income and occupation), description of the medications requested, and the following guiding questions: *Tell me how it was for you to have access to the medication you/your family member needed. What path did you have to take to get access to the medicine? How was the experience of going to court to get access to the drug?*

Interpretative thematic analysis was conducted in a continuous process concomitant with data collection, in six stages[10]: familiarization with the data; identification of codes; grouping of codes into thematic nuclei; revision of nuclei; definition and final naming of nuclei; and elaboration of the description and interpretation of the meanings expressed by the participants in each nucleus.

Three criteria were used to ensure reliability of the data analysis: (1) recording of the interviews, and checking of transcripts by the first two authors of the study; (2) confirmation, with the participants, of the descriptions at the end of the interviews; and (3) confirmation of the codes and thematic nuclei, which were checked among the members of the research team throughout the data analysis process[11]. The entire process of interpretation was conducted collectively through discussion, review and re-elaboration of descriptions and interpretations.

The study was approved by the Research Ethics Committee of the Pontifical Catholic University of Goiás under protocol no. 1933/2011. The anonymity of the participants was protected by fictitious names and all signed the Informed Consent Form.

RESULTS AND DISCUSSION

The nine participants sought the guarantee of access to the drugs through two routes. In the first, six participants initially asked the Municipal Health Department to obtain the medications. Once they knew that the prescribed drugs were not present on the official lists, it was necessary to open an administrative process. This process was marked by delay and lack of embracement, aspects that motivated users to appeal to the Prosecution Office to propose lawsuits against the municipality, in order not to hamper their therapeutic plans, and to ensure resolution of access.

In the second route, two users directly sought access to the prescribed drugs through the Prosecution Office. The Public Prosecutor filed lawsuits against the municipality, setting a deadline for compliance. It is noteworthy that in these processes, there were medications that were not on the official lists, but others were provided and could be made available through the SUS process.

The interpretative analysis verified that the experiences of SUS users around guaranteeing access to prescription drugs was characterized by a process that involved persistence, family support, and the need to ensure the right to health of people whose chronic conditions demand complex and long-term care. The following thematic nuclei related to access to medications were identified from the perspective of users: attempts to access the drugs through an administrative process, with deficits of information in embracement, and delays in the response of the process; and obtaining the drugs through a court proceedings, characterized as a "difficult process, but with embracement and resolution":

Attempts to access the drugs through an administrative process, with deficits in information and embracement, and delays in responses to the process

The codes grouped in this nucleus were related to lack of information provided to the users in the search for the drugs, difficulties with embracement by professionals, and delays in responses to the administrative process.

To file an administrative process in the municipality, users must seek help from the Social Welfare Department, and meet the following requirements: provide proof of residency in the city and present the prescription and the medical report that justifies it. Also, the drug must not belong to the RENAME in force. It was found that, among the eight cases analyzed, six users initially tried to obtain the drugs through an administrative route and, after

not being successful, decided to resort to legal proceedings.

The participants reported physical, cognitive and social limitations associated with their chronic health conditions (epilepsy, Alzheimer's disease, autoimmune hepatopathy, Cushing's disease, coronary insufficiency, cerebral atrophy and Parkinson's disease) as factors in continuous use of the medications. Some users justified their need based on the claim that failure to access the drugs could lead to worsening of their health condition. In addition, financial difficulty was one of the motivating factors for demanding access to the drugs through SUS:

> [...]My wish was not to depend on any pills! I think that's what everyone wants! And it's not good! But when we need to take one, we will soon need two! As I know that my problem has no cure (epilepsy), I have to take the pills for the rest of my life! (Hélio).

> [...] he (doctor) prescribed this medication (memantine hydrochloride), I went to the pharmacy to buy it, I thought it was very expensive! I think it was about R$70.00! With the money, we cannot afford it! We are both retired, we get tiny money! (Marta's husband).

Chronic conditions, associated with financial limitations, were reported by users to be determining factors for requiring access to medications in the public health system, so it is important that the State establish public policies that guarantee access, especially to those of lower income, promoting care comprehensiveness and resolution[12].

Brazil is a country that has set up guarantees of access to medications and universal health coverage in its management policies. Several public policies have been developed, such as the National Drug Policy in 1998, the Generic Drug Act in 1999, the National Policy on Pharmaceutical Assistance in 2004, and the creation of the Popular Pharmacy Program, also in 2004. However, advances in the selection and incorporation of new medications are still necessary, as well as in the effective use of public resources for their financing[13].

Some Latin American countries also face challenges to ensuring access to medications, such as low levels of coverage, financial fragility of health systems, limitations in drug distribution, and problems in accessing health services. It is noted that this difficulty is a global issue[14]. The World Health Organization proposes an access model that considers four dimensions: availability, physical accessibility, economic accessibility, and user satisfaction. Ensuring these conditions is a major challenge because it requires an integrated and permanent approach from health managers[15].

Some dimensions related to access to the drugs in SUS routine pathways were not observed in this study, such as financial accessibility and unavailability of medications, or even absence in the official lists, which motivated the participants to seek the administrative route. Realities such as these demonstrate the inadequacy of public health policies[5].

The participants mentioned that lack of embracement and information demanded numerous trips to the health services to file the administrative process in the Social Service of the municipality. Bureaucracy and failure to correctly fill in reports and medical prescriptions also made the filing process difficult. The interviewees considered this disrespectful, especially having to go to different places, and what documents to take:

[...] it was hard to get the report because the doctor did it wrong, wrote a wrong prescription! He had to do it again, you know? Then I had to go back to the Health Department (to start the administrative process), doing everything again, because it has to be right, ok? You have to do the report and say what the disease is, what you need, what it's like, what it's not, that sort of thing! (Sister of Lázaro).

> [...] you look like a ping-pong ball! Sometimes, they send you to the Health Department, there they send you to the social worker [...] (Gustavo).

The growing demand for administrative procedures has led to the establishment of protocols to standardize the filing of proceedings by the executive branch, such as the requirement for prescriptions and medical reports. This standardization guarantees the financial sustainability of the health system but also constitutes a barrier to access to the medications, often due to lack of transparency and effective communication in operational procedures and the time required to fulfill requests. The phenomenon of institutionalization of the

administrative route may indicate inequities in access to health in a fragile and low-resolving system[16].

It was also shown that healthcare professionals directly involved in this path did not fulfill certain responsibilities, such as the obligation to adequately fill out the necessary documents for initiating the process. In addition, they did not provide information to users about the way the process is handled in the administrative instance, either by ignorance or by negligence. It is up to the professionals involved to know these protocols and execute them efficiently, without the need for users and their families to be informed about the procedures that should be performed.

Although the administrative route is formally instituted by the executive branch, there are still few studies about it[6]. Therefore, the need for management of the Brazilian health system to resolve issues related to access to medications in SUS is highlighted. This could contribute to better effectiveness and therapeutic proportionality in meeting individual and, especially, community (society) needs.

The participants mentioned feelings of humiliation and not being paid attention to in constantly seeking answers about the administrative process:

> [...]You feel bad, [...] you feel inferior! I do not even know how to express it, it's a very bad feeling, humiliation! We have to get to a lower level to get something (get the medication by the administrative route) [...] (Luiza).

It is important to improve knowledge of continuity of care in healthcare systems, with a view to establishing procedures for communication, follow-up and information about care needs along therapeutic itineraries. For this, it is essential to make health professionals aware of the need to improve communication among the teams involved in accessing medications, in order to establish a dialogue between prescribers and dispensers[17].

Physicians, nurses, pharmacists and social workers, in particular, should act in an integrated way to welcome users and guide them through access to medications. Adequate information leads to agility in the process and becomes the central element in understanding the dimensions of access, as a result of communication between the health system and the individual.

It should be emphasized that welcoming does not mean receiving and verifying the documentation necessary to open the process, but rather providing consistent information, checking the users' understanding, and clarifying doubts about the progress of the process. These are measures that could help healthcare services achieve greater resolution and legitimacy with users.

In addition, considering the national drug policy[18] and the pharmaceutical assistance program[19], users need to be informed about which drugs are on the official SUS lists, the protocols for access to them, and where they are available. RENAME should be a guiding tool for health care, to improve the quality of the care provided, training of prescribers, and citizens' information[4].

User dissatisfaction was another barrier to access, particularly regarding delays in responses in the administrative route. Because it is a system with universal coverage, SUS should provide mechanisms for resolution. It is important to facilitate and optimize response times in the administrative process, considering the chronic conditions presented by all the participants. Since such care is not always offered resolutely for the needs of sick people, it is necessary to undertake new search paths[12].

This scenario demonstrates that barriers to drug access are interconnected at different levels in health systems[20], because the participants in this study, who are living with chronic diseases and need continuous medication, need the health services. It is therefore necessary to assess access not only to the medications, but also to these services.

Obtaining the drug through a judicial process: "a complicated process, but with embracement and resolution"

The units of meaning grouped in this nucleus related to lack of information offered to users in their search for the drugs through judicial proceedings, good embracement provided by professionals, and resolution.

There was also lack of information for users in judicial proceedings, which resulted in multiple trips to the prescribers to get more detailed reports and justify the criteria established for the use of the medications.

Although there is a protocol for filing lawsuits, there are still failures in user information:

> [...]What was difficult in getting the medication was to have to walk from side to side, the walks, I had to go to the courthouse, chasing after the prescription and the report with the doctor! Then go to the courthouse again, come back, have to get another prescription and put some letters there that I don’t know the name [...] it is difficult for us, who are already a certain age (66 years), to travel by bus! As I told you, I have a free pass, but it is not easy for us, who are retired, to get all those documents they require! I'm not lazy, but sometimes all this paperwork makes us walk a lot, search on one side, then search on the other, it's not easy, right! (Marta’s husband).

It is important that professionals involved in the judicial process provide clear and objective information to users on the necessary documentation, seeking to facilitate access. As in the administrative process, the beginning of the court proceedings was marked by failures in information about documentation. However, satisfaction with the court proceedings was unanimous, mainly due to resolution and good service. Many subjects reported that they were only able to obtain the drugs after using this route:

> [...]The Prosecution Office for me was the best way because I was well-received, as I have already said, by people who are human [...] (Gustavo).

> [...] I think that looking to the judicial branch solved my wife's problem! In my opinion it was an agile way! [...] the problem is solved much faster! [...] after a month I had already gotten the medicine! (Nilva’s husband).

> [...] we had to go to court to get a medication! [...] only after my daughter went to the Prosecution Office, took some documentation there, medical report, prescription, copy of some exams, did we start to get the medication and get it today! (Eliane’s mother).

In the judicial route, the participation of the Prosecutor’s Office was highlighted as a legal entity that could be sought by people with chronic diseases and their relatives, when the right to health was not guaranteed(21). The Prosecutor’s Office used public civil action and filed lawsuits against the municipality.

It is noted that the Prosecutor’s Office gave users the possibility of being active subjects and participants in their decisions. This perspective highlights the importance of the concept of empowerment, defined as a process in which people or communities acquire greater control over decisions and actions that affect their health(22).

Users considered the judicial proceedings to lead to resolution, mainly regarding shorter waiting times when compared to the time for the administrative route. A study by Sant'ana et al.(3) also described the judicial route as the fastest and least bureaucratic, and therefore more attractive to users. This contributed to satisfaction, as described in this study.

Access to drugs can demonstrate whether the health system is prepared to fully address these issues and show whether universal access is in practice. In Brazil, several barriers are still evident in healthcare systems, regarding financing, human resources, information and services(20).

Knowing the path taken by users is useful in defining strategies for planning, organization and evaluation of healthcare services since itineraries in the search for therapeutic care do not necessarily coincide with flowcharts pre-established by the public health system(23).

Understanding the factors that make compliance with therapeutic itineraries difficult is a way of welcoming users who seek services, reducing the number of judicial and administrative demands for medications, as well as proposing improvements and alternatives for the work and the healthcare professionals involved, to meet user expectations.

In addition, public managers should favor the work of health teams through the elaboration and implementation of protocols for dispensing medications, considering guidelines for welcoming users who seek care. It is essential that professionals who are directly related to access to drugs interact, including physicians, pharmacists, nurses and social workers.

The present study revealed substantial barriers to access to medications in SUS; the main barrier was lack of information for users. If users were advised of the availability of prescribed medications and how the process of administrative proceedings works, judicial proceedings could be avoided. Information is

needed to understand the dimensions of access, so it should be improved.

Access to medications in SUS still presents some flaws, so it is critical to implement strategies to increase access and reduce inequalities. Some measures could minimize these problems and ensure the availability of items on essential drug lists: reassessment of drug acquisition, stocking and dispensing routines; expansion of the Popular Pharmacy Program, which would increase the number of pharmacies and products available; and reductions in the prices of generic drugs[5].

Other measures have been adopted in several states in Brazil, such as the creation of agreements between legal and political institutions, such as conventions, technical chambers and mediation chambers[13], the purpose of which is to rationalize the increasing use of judicial proceedings and mitigate deficits related to access to medications.

FINAL CONSIDERATIONS

The results pointed to barriers to access to medications related to the financial difficulties of users, embracement by professionals, and delays in responses of the process in the administrative route. In judicial proceedings, the main barrier was lack of information provided to users in the search for drugs; however, users felt satisfied, considering embracement and resolution of the process demanded.

This scenario reflects the difficulty of public management in guaranteeing access to medications in the Brazilian public health system, and contributes to a critical reflection on the perceptions of users about this access. Interventions focused on the needs of individuals, families, and communities are required, as well as compliance with the organizational and doctrinal principles of the Unified Health System.

The reality experienced by these people evidenced the need to adopt models of integrated health care that favor coordination and continuity among the different levels of health care. The establishment of an empathic relationship between health professionals and users, the provision of information regarding prescribed drugs, and the revision and continuous updating of official drug lists could optimize the time between users' requests and the availability of drugs in the system. Therefore, it is necessary to qualify healthcare professionals to understand the protocols for access to medications in the Unified Health System.

Complexity related to access to medications in universal health systems indicates the need for research that deepens the understanding of this problem, which involves users, professionals and managers of public health, in the search for strategies that guarantee equal rights regarding individual and collective health.

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ACESSO AO MEDICAMENTO: PERSPECTIVAS DE PESSOAS QUE RECORRERAM À VIA JUDICIAL

RESUMO

Trata-se de um estudo de caso interpretativo desenvolvido com o objetivo de descrever as experiências de pessoas que recorreram à via judicial para ter acesso a medicamentos no Sistema Único de Saúde. Os dados foram coletados por meio de entrevista semiestruturada nos domicílios de oito pessoas que recorreram a essa via, residentes em um município localizado no sudoeste do Estado de Goiás. A experiência de acesso ao medicamento foi marcada por barreiras que estão interligadas aos diversos níveis do sistema de saúde; envolvem aspectos organizacionais e assistenciais relacionados à informação, ao acolhimento e à resolutividade. A necessidade do tratamento contínuo da condição crônica e a dificuldade financeira foram os fatores determinantes para que os participantes recorressem à justiça. Observou-se a necessidade de aprimorar o acolhimento e a comunicação entre a equipe de saúde envolvida no acesso ao medicamento e de qualificar os profissionais da saúde para uma compreensão ampliada da assistência farmacêutica no Sistema Único de Saúde.

Palavras-chave: Direito à saúde. Assistência farmacêutica. Acesso aos serviços de saúde. Sistema Único de Saúde.

ACCESO AL MEDICAMENTO: PERSPECTIVAS DE PERSONAS QUE RECURRIERON A LA VÍA JUDICIAL

RESUMEN

Se trata de un estudio de caso interpretativo desarrollado con el objetivo de describirlas experiencias de personas que recurrieron a la vía judicial para tener acceso a medicamentos en el Sistema Único de Salud de Brasil. Los datos fueron recolectados por medio de entrevista semiestructurada en los domicilios de ocho personas que recurrieron a esta vía, residentes en un municipio ubicado en el sudoeste del Estado de Goiás. La experiencia de acceso al medicamento fue marcada por obstáculos que están interconectados a los diversos niveles del sistema de salud; involucran aspectos organizacionales y asistenciales relacionados a la información, acogiday resolutividad. La necesidad del tratamiento continuo de la condición crónica yla dificultad financiera fueron los factores determinantes para que los participantes recurrieran a la justicia. Se observól a necesidad de perfeccionar la acogiday comunicación entre el equipo de salud involucrado en el acceso al medicamento y de calificar a los profesionales de la salud para una comprensión ampliada de la asistencia farmacéutica en el Sistema Único de Salud.

Palabras clave: Derechoa la salud. Asistencia farmacéutica. Acceso a los servicios de salud. Sistema Único de Salud.

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